

REMARKS

Personal Interview with the Examiner

Applicants wish to thank the Examiner for the courtesies extended during the personal interview held on May 6, 2008.

During the above referenced interview, the Examiner indicated that favorable reconsideration might be possible if the position of the head or enlarged integral portion of the securing member was defined as being within the posterior bore portion posterior to the stopping member. Applicants have clarified the un-allowed claims to call for the stopping member to have a posterior stopping surface which retains the head or enlarged integral portion of the securing member within the posterior bore portion posterior to the stopping member.

Response to Claim Rejections Under 35 USC §112

Claims 52-58 were rejected by the Examiner under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner indicated that "the securing member" found in claim 52 and "the securing element" found in claim 54 lack antecedent bases. In response applicants have amended claims 52 and 54 to avoid this rejection.

Response to Claim Rejections Under 35 USC §102

Claims 1-3, 9-11, 16-17 and 19 were rejected by the Examiner under 35 USC §102(b) as being anticipated by Dill (U.S. Pat. No. 5,118,235). The Examiner contends that this reference describes a biased stopping member 80. However, the curved lip 80,

which the Examiner identifies as a biased stopping member, is not disclosed as being biased or a stopping member as these terms are used in applicants' application. Specifically, the lip 80 is described as a locking element for flap 90. The flat is flexible and is configured to act as a stop for the screw head (24) (col. 5, lines 40-51) not the lip 80 as contended by the Examiner. Moreover, the Dill patent is silent as to a stopping member defining at least in part a reversibly expandable passageway having a larger diameter configuration to allow the head of the securing member to pass into the posterior bore portion and a smaller diameter configuration to facilitate retention of the head of the securing member within the posterior bore portion. The Examiner cites column 3, line 33 to column 4, line 16 of the Dill patent for support, but the cited section does not mention the lip 80 and provides no teaching which relates to the lip 80. The flap 90 is described as being flexible and acting as a stopping member, but the flap closes off the passageway so it could not define at least in part a reversible expandable passageway as called for in claim 1.

Applicants believe that the Examiner has looked at Fig. 7 alone in rejecting claims 1-3, 9-11, 16-17 and 19 when Figs. 1-6 should also have been considered, particularly Fig. 6. Fig. 6 shows that the anterior opening in the washer is longer than its width. The head of the screw could be anywhere within the opening and the transverse cross section shown in Fig. 7 would not define the position of the screw head within the washer. Moreover, in view of the tapered posterior surface of the screw head, the head of the screw would very likely be urged sideways in the event that the underside engages the upper surface of the element 80. Additionally, once the screw head is disposed within the posterior bore, the tapered posterior surface of the element 80

would not act as a stopping surface (anymore than the tapered anterior surface of element 80 stopped the screw head from passing through anteriorly). Furthermore, with the edges of the stopping element 90 locked in place under element 80, the head of the screw could not engage the posterior surface of the element 80. If the stopping member 90 was not locked under the element 80, the tapered posterior surface of the latter would not stop the screw from backing out, so it cannot be considered as a stopping member as contended by the Examiner.

Applicants submit that the Dill reference fails to teach every feature of the rejected claims and as a result fails to support the Examiner's rejection under 35 USC §102(b).

However, to clarify claim 1, applicants have amended the claim to call for the stopping member to have a posterior stopping surface which retains the screw head within the posterior bore portion.

The Examiner contends that the recitation of "An orthopedic implant assembly" in the preamble is not a limitation because the believes that the body of the claim fully and intrinsically sets forth all of the limitations of the claim invention, citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*¹ and *Rowe v. Dror*². However, the cited cases were distinguished by the Federal Circuit in a more recent case (*Poly-America, L.P. v. GSE Lining Technology, Inc.*³) wherein the court stated

Whether to treat a preamble as a limitation is a determination resolved only on review of the entire patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.

¹ 182 F. 3d 1298, 1305, 51 USPQ2d 1161,1165 (Fed. Cir. 1999)

² 112 F. 3d 473, 478, 42 USPQ2d 1550,1553 (Fed. Cir. 1997)

³ 383 F. 3d 1303 (Fed. Cir. 2004)

The Court concluded that when the phrase in the preamble is used repeatedly to describe the preferred embodiments and when the inventor considered the preamble language represented an important characteristic of the claim invention, then the preamble does not state a purpose or intended use of the invention, but rather discloses a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim itself.

In the present application, applicants have used the terms orthopedic attachment or orthopedic implant continuously throughout the specification and clearly describes a fundamental characteristic of the invention, namely an assembly for attachment to one or more bones.

Claims 29, 31, 33-36, 42-47, 60, 102, 106 and 114 were rejected by the Examiner under 35 USC §102(b) as being anticipated by Hodorek (U.S. Pat. No. 5,534,032). The Examiner contends that sealing solid washer 200 is a biased stopping member. While applicants understand that the Examiner must take a broad interpretation of claim language, the broad interpretation must be reasonable and consistent with applicants' specification. From the present specification it is clear that the stopping member does not occlude the bore of the attachment member as does the sealing washer 200 of Hodorek. It is clear that the stopping member of the present invention is configured to allow for the passage of the head or the enlarged integral portion of the securing member to pass into the posterior bore portion and to retain the head or enlarged integral portion within the posterior bore portion. To conclude that element 200 of the '032 patent is a stopping member that reduces the transverse configuration of the bore and would allow such passage into the posterior bore portion is

believed to be an unreasonable interpretation of the claim that is not consistent with the specification. To clarify this feature, Applicants have amended claims 29, 63, 89, 94 and 96 to call for the stopping member to allow the head or enlarged integral portion of the securing member to pass through the stopping member into the posterior bore portion and to have a posterior stopping surface to facilitate retention of the head or enlarged integral portion within the posterior bore portion. The sealing washer 200 of Hodorek fails to meet the requirements of these claims, so the rejection is not supported by this reference.

Claims 29-31, 33-37, 39-40, 42-48, 60, 89-95, 102, 105 and 114 were rejected under 35 U.S.C. 35 USC §102(b) as being anticipated by Hodorek (U.S. Pat. No. 5,534,032). Apparently, the Examiner contends that element 20 is a resilient stopping member as called for in the claims. However, as mentioned above, these claims require that the stopping member allow the head or enlarge integral portion to pass into the posterior bore portion of the attachment or stabilizing member and to have a posterior stopping surface to retain the head or enlarged integral portion within the posterior bore portion. The reference does not teach this feature and therefore does not meet all the requirements of the claims so the reference does not support the Examiner's rejection.

Claims 29, 31, 36, 42-48, 50 and 89-105 were rejected by the Examiner under 35 USC §102(e) as being anticipated by Richelsoph (U.S. Pat. No. 6,017,345).

The above rejected claims call for the stopping member to allow passage of the enlarged head or integral enlarged portion into the posterior bore portion and to have a posterior stopping surface to retain the enlarged head or integral enlarged portion within

the posterior bore portion. The Examiner contends that element 28 of the '345 patent is a stopping member or a resilient member, but the element 28 does not allow the head or enlarged integral portion of the securing member to pass into the posterior bore portion and it does not have a posterior stopping surface to retain the head or enlarged integral portion within the posterior bore portion, so this feature of the rejected claims is not taught by the '345 patent.

Claims 1, 10-17, 29, 31, 33, 36, 42-50, 52-53, 60, 63-79, 89-96, 99-103, 106 and 114 were rejected by the Examiner under 35 USC §102(b) as being anticipated by Estes (U.S. Pat. No. 5,578,034). The Examiner contends that stopping member 16 reduces the transverse configuration of the bore, defines at least in part the posterior bore portion to retain the enlarged integral portion of the securing member and wherein the collar is formed of an elastically deformable or superelastic material.

However, there are substantial deficiencies in the '034 patent. The first is that the securing member is held in the bore by treads and the head or enlarged portion of the securing member is not retained within the posterior bore portion between the biased stopping member and the posterior opening of the stabilizing element. Moreover, the claims call for the stopping member to allow the head or enlarged integral portion of the securing member to pass into the posterior bore portion and to retain the head or enlarged integral portion within the posterior bore portion. The '034 patent fails to teach these features, so the rejection is not supported by this reference.

With respect to claims 69 and 70, the Examiner contends that the enlarged integral portion of the Estes securing member is capable of expanding the collar if it is pushed through the collar. The Examiner further contends that the expression "adapted

to” or “configured to” requires only the ability to so perform and does not constitute a limitation in any patentable sense. However, a key issue is the ability to perform. Fig. 1 clearly shows that the head 20 of the Estes securing member cannot be pushed through the collar or stopping member 16. The tapered top portion 24 of bore 18 of the Estes device prevents the securing member from being pushed through the stopping member 16. Moreover, the stopping member 16 is mounted onto the shaft of the securing member after the securing member is inserted into the attachment or stabilizing member. With the threaded connection between the shaft of the securing member and the stopping member 16, pushing on the securing member will merely push the stopping member 16 out the posterior port in the attachment member. There is no way the device of Estes can be considered as teaching all the features of applicants’ claims.

Response to Claim Rejections Under 35 USC §103

Claim 49 was rejected by the Examiner under 35 USC §103(a) as being unpatentable over Hodorek ('032) and Richelsoph ('345). Claim 49 depends indirectly from claim 29 and, as discussed above, neither Hodorek nor Richelsoph teach all the features of claim 29 so these references would not teach all the features of claim 49 which includes the features of claim 29.

Response to Allowable Subject Matter

The applicants note with appreciation the Examiner’s indication that claims 4-8, 18, 20 and 51-58 are directed to patentable subject matter and the allowance of claims 21-28, 59, 84-86, 88 and 107-113.

New Claims 115-119

Applicants have added new claims 115-119 which are directed to the embodiment shown in Figs. 5, 6, 10-12, 14 and 15 and the description found in col. 5, lines 46 -67, col. 6, lines 50-54 and col. 7, lines 19-22. The length of the enlarged integral portion of the securing member is less than the length of the posterior bore portion between the stopping member and the smaller dimension of the posterior bore portion to facilitate movement of the securing member within the posterior bore portion. Moreover, the transverse dimension of the posterior opening is larger than the shaft of the securing member to facilitate angular displacement of the head or enlarged portion of the securing member within the posterior bore portion. The features of these claims are not described in the cited prior art. No new matter is introduced by the addition of these new claims. The chart filed herewith pursuant to 37 C.F.R. §1.173(c) lists the locations in the specifications which support the new claims.


Conclusions

Applicants have included herewith a listing of all claims, including the claims present in the original patent and a Mark-Up Of Amended Claims which indicates the changes made to the claims in the new amended claim pages.

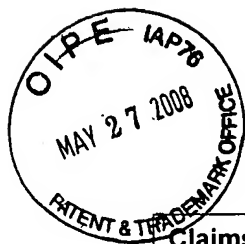
Applicants have also included a chart pursuant to 37 C.F.R. §1.173(c) listing the status and support for the all claims not found in the issued patent and amendments thereto.

Applicants believe that the pending claims define patentable subject matter and warrant an early allowance.

Respectfully submitted:

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**Status And Support For All Claims Not Found In Issued Patent
And Amendments Thereto Pursuant To 37 CFR §1.173(c)**

Claims	Status	Support (Ref. to Issued Patent)
Claim 1	Amended	Col. 4 lines 48-55 (amendment)
Claim 2	Original	
Claim 3	Original	
Claim 4	Original	
Claim 5	Original	
Claim 6	Original	
Claim 7	Original	
Claim 8	Original	
Claim 9	Original	
Claim 10	Original	
Claim 11	Original	
Claim 12	Original	
Claim 13	Original	
Claim 14	Original	
Claim 15	Original	
Claim 16	Original	
Claim 17	Original	
Claim 18	Original	
Claim 19	Original	
Claim 20	Original	
Claim 21	Original	
Claim 22	Original	
Claim 23	Original	
Claim 24	Original	
Claim 25	Original	
Claim 26	Original	
Claim 27	Original	
Claim 28	Original	
Claim 29	Twice Amended	Figs. 1-6; Col. 4, line 13-col. 6, line16; Figs13-15
Claim 30	Twice Amended	Figs. 3-5; Col. 4, line 64-col 5, line 30

Claims	Status	Support (Ref. to Issued Patent)
Claim 31	Pending	Fig. 5, Col 4; line 64-col. 5, line 20
Claim 32	Cancelled	Cancelled
Claim 33	Pending	Fig. 5; Col.5, lines 59-67
Claim 34	Pending	Figs. 1-6
Claim 35	Pending	Figs. 1-6
Claim 36	Pending	Fig. 3; Col. 1, lines 42-55
Claim 37	Twice Amended	Fig. 4; Col.1, lines 45-47; Col. 5, lines 2-15
Claim 38	Pending	Figs. 3-5; Col.4, lines 31-33
Claim 39	Pending	Figs. 2-5
Claim 40	Pending	Fig. 13
Claim 41	Cancelled	Cancelled
Claim 42	Pending	Figs. 5-6; Col. 5, lines 46-67
Claim 43	Pending	Fig. 1
Claim 44	Pending	Fig. 1; Col. 7, lines 52-57
Claim 45	Pending	Col. 7, lines 47-57
Claim 46	Pending	Col. 7, lines 49-52
Claim 47	Pending	Col. 2, lines 6-8
Claim 48	Pending	Col. 6, lines 1-3
Claim 49	Pending	Col. 6, lines 1-3
Claim 50	Pending	Figs. 2-6
Claim 51	Pending	Figs. 3-5
Claim 52	Twice Amended	Col. 2, lines 19-46
Claim 53	Pending	Col. 2, lines 61-67
Claim 54	Twice Amended	Figs. 7-12; Col. 6, lines 17-54
Claim 55	Pending	Figs 8 and 10. Col. 6, lines 31-50
Claim 56	Pending	Figs. 7-12
Claim 57	Pending	Figs. 7, 8 and 10
Claim 58	Pending	Figs. 8, 10 and 12
Claim 59	Pending	Figs. 7-12; Col. 2, lines 46-60
Claim 60	Pending	Figs. 2, 3, 4, 5 and 6; Col. 5, lines 30-42
Claim 61	Cancelled	Cancelled
Claim 62	Cancelled	Cancelled
Claim 63	Twice Amended	Figs. 1-6; Col. 4, line 13-col. 6, line16; Figs13-15; Col. 5, lines 51-59

Claims	Status	Support (Ref. to Issued Patent)
Claim 64	Pending	Col. 5, lines 21-30
Claim 65	Twice Amended	Col. 5, lines 15-20
Claim 66	Pending	Col. 5, lines 2-8
Claim 67	Pending	Col. 5, lines 30-33
Claim 68	Pending	Figs. 3, 4 and 5; Col. 4, lines 31-33
Claim 69	Pending	Fig. 4; Col. 5, lines 2-8
Claim 70	Twice Amended	Fig. 4; Col. 5, lines 2-8
Claim 71	Pending	Figs. 13-14; Col. 6, lines 55-67
Claim 72	Pending	Fig. 14
Claim 73	Pending	Fig. 14
Claim 74	Pending	Fig. 6; Col 5, lines 46-67
Claim 75	Pending	Fig. 1; Col 7, lines 62-67
Claim 76	Pending	Fig. 1, Col 7, lines 52-57
Claim 77	Pending	Col. 7, lines 52-57
Claim 78	Pending	Col. 7, lines 49-52
Claim 79	Pending	Col. 2, lines 6-8
Claim 80	Cancelled	Cancelled
Claim 81	Cancelled	Cancelled
Claim 82	Cancelled	Cancelled
Claim 83	Cancelled	Cancelled
Claim 84	Pending	Figs13-15; Col. 5, lines 51-59
Claim 85	Pending	Figs13-15; Col. 5, lines 51-59
Claim 86	Pending	Figs13-15; Col. 5, lines 51-59
Claim 87	Cancelled	Cancelled
Claim 88	Pending	Figs. 8, 10 and 12
Claim 89	Twice Amended	Figs. 1-6; Col. 4, line 13-col. 6, line16; Figs 7-12; Col. 6, lines 16-54; Col. 7, lines 62-67
Claim 90	Pending	Fig. 3; Col. 1, lines 42-55
Claim 91	Twice Amended	Fig. 3; Col. 1, lines 42-55
Claim 92	Pending	Figs. 3-5; Col.4, lines 31-33
Claim 93	Pending	Col.2, lines 61-67
Claim 94	Twice Amended	Figs. 7-12; Col 2, lines 46-60; Col. 7, lines 62-67
Claim 95	Twice Amended	Figs. 7-12; Col 2, lines 46-60; Col. 7, lines 62-67
Claim 96	Twice Amended	Figs. 7-12; Col 2, lines 46-60; Col. 7, lines 62-67

Claims	Status	Support (Ref. to Issued Patent)
Claim 97	Cancelled	Cancelled
Claim 98	Twice Amended	Figs. 7-12; Col 2, lines 46-60; Col. 7, lines 62-67
Claim 99	Pending	Figs. 7-12; Col 2, lines 46-60; Col. 7, lines 62-67, Figs. 2-6, lines Col. 4, line 13-col. 6, line16
Claim 100	Pending	Figs. 7-12; Col 2, lines 46-60; Col. 7, lines 62-67; Figs. 2-6, lines Col. 4, line 13-col. 6, line16
Claim 101	Pending	Figs. 7-12; Col 2, lines 46-60; Col. 7, lines 62-67; Figs. 2-6, lines Col. 4, line 13-col. 6, line16
Claim 102	Twice Amended	Figs. 5 and 6; Col. 2, lines 34-38
Claim 103	Cancelled	Cancelled
Claim 104	Twice Amended	Col. 4, lines 31-33; Col. 6, lines 1-3
Claim 105	Pending	Figs. 4-5; Col. 5, lines 15-20
Claim 106	Pending	Figs. 5-6, lines 51-67
Claim 107	New	Figs. 7-12; Col. 6, lines 17-54
Claim 108	New	Figs. 2-12; Col 6, lines 17-54; Col. 7, lines 62-67
Claim 109	New	Col. 6, lines 1-2; Col. 7, lines 62-67
Claim 110	New	Col. 1, lines 42-67; Col. 7, lines 62-67
Claim 111	New	Figs. 7-12; Col. 6, lines 17-54
Claim 112	New	Figs. 7-12; Col. 6, lines 17-54
Claim 113	New	Figs. 7-12; Col. 6, lines 17-54
Claim 114	New	Fig. 5; Col. 5, lines 46-51
Claim 115	New	Figs. 5, 6, 10-12, 14 and 15; Col. 5, lines 46 -67, Col. 6, lines 50-54 and Col. 7, lines 19-22.
Claim 116	New	Figs. 5, 6, 10-12, 14 and 15; Col. 5, lines 46 -67, Col. 6, lines 50-54 and Col. 7, lines 19-22.
Claim 117	New	Figs. 5, 6, 10-12, 14 and 15; Col. 5, lines 46 -67, Col. 6, lines 50-54 and Col. 7, lines 19-22.
Claim 118	New	Figs. 5, 6, 10-12, 14 and 15; Col. 5, lines 46 -67, Col. 6, lines 50-54 and Col. 7, lines 19-22.
Claim 119	New	Figs. 5, 6, 10-12, 14 and 15; Col. 5, lines 46 -67, Col. 6, lines 50-54 and Col. 7, lines 19-22.